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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation - New- Agency for Toxic Substances and Disease Registry (ATSDR) and Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Navajo Nation includes 16 million acres of New Mexico, Utah and Arizona. It is the largest Alaska Native/American Indian Reservation in the United States. From 1948 to 1986, many uranium mining and milling operations took place in the Navajo Nation, leaving a large amount of uranium contamination on the reservation. Several studies have reported that uranium mostly damages the kidneys and urinary system. However, there is not much research data on uranium exposure and poor birth and reproductive health outcomes. Research involving prenatal exposure to uranium may help to understand and prevent some unfavorable child and maternal health outcomes.

There are important health differences concerning birth outcomes and prenatal care in the Navajo Nation. According to the Indian Health Service *Regional Differences in Indian Health 2002-2003 Edition*, the infant death rate among the Navajo people is 8.5 deaths per 1000 live births, compared to 6.9 deaths per 1000 live births among all races. Only 61% of Navajo mothers with live births received prenatal care in the first trimester as compared to 83% of all US mothers. Early and regular prenatal care is a major predictor of positive birth outcomes. Due to the health differences in birth outcomes and the chance for environmental uranium exposure in the Navajo Nation, ATSDR decided that the upcoming study must include education of women

and their families about the importance of prenatal care and the potential poor health risks associated with exposure to uranium.

The House Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation. As a result of this request, ATSDR awarded a research cooperative agreement to University of New Mexico Community Environmental Health Program (UNM-CEHP) entitled "A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01)," in August 2010. ATSDR and UNM-CEHP are working with the Navajo Area Indian Health Service (NAIHS), Navajo Nation Division of Health (NNDOH), Navajo Nation Environmental Protection Agency (NNEPA), and Navajo culture and language specialists to carry out the study. The study will examine reproductive outcomes in pregnant women, follow and assess their children from birth to 1 year of age, and create a system to follow up the infants through childhood up to 6 years of age to evaluate the impact of uranium exposure on biological and psychosocial endpoints. Biological sample analysis, surveys, and developmental screenings will be performed during this research period for each participant.

In addition to investigating the role of uranium and other chemicals in the environment on birth outcomes and development, the prospective study may aid in understanding causes and

prevention measures of chronic conditions. Several research studies have shown that exposure to chemicals in the environment during prenatal and postnatal periods can affect the development of adult chronic diseases. The study will also provide broad public health benefits for Navajo communities through outreach and education on environmental prenatal risks and early assessment. Referrals will also be provided for known developmental delays.

Participants will include Native American mothers from age 14 to 45 with verification of pregnancy who have lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of the healthcare facilities that are taking part in the study (Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility, Gallup Indian Medical Center, Tuba City Regional Health-Care Corporation, or Tséhootsooí Medical Center). Fathers will be included in the study with consent regardless of age or residence. We estimate that 550 pregnant women and fathers per year must be enrolled in the study to obtain adequate statistical power. A 10% pregnancy loss will be assumed, which would result in 500 live births per year. Therefore, the total anticipated sample size is 1,500 mother-infant pairs over the three years of the study.

The data collection instruments for pregnant mothers include the following: Enrollment Survey, Ages and Stages Questionnaire (ASQ-I), Mullen Stages of Early Development (MSEL), Postpartum Surveys (12 month Postpartum survey includes Nutritional Assessment/Food Intake Questionnaire) and Eligibility Form. An enrollment survey for fathers who agree to participate will also be administered. Community Health and Environmental Research Specialists (CHERS) will administer surveys using a CDC-approved electronic data entry system. Survey instruments were designed to collect demographic information, assess potential environmental health risks, and mother-child interactions. The survey instruments were developed based on previous surveys conducted by Dine' Network for Environmental Health (DiNEH) Project, the National Children's Study, and by other birth cohort studies that have been conducted among other indigenous populations. The final format of the survey instruments was modified based on review and input from the Navajo Nation community liaison group and associated Navajo staff to address issues such as cultural sensitivity, comprehension and language translation.

There is no cost to the respondents other than their time to participate in the study. The total estimated annual burden hours are 3596.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (Hours)
Mother	Enrollment Survey	550	1	120/60
	Ages and Stages Questionnaire (2,6,9 12 months)	500	4	15/60
	Mullen Stages of Early Development	500	1	15/60
	Postpartum Survey (0 months)	500	1	60/60
	Post-partum Survey (2,6,9 months)	500	3	15/60
	Postpartum Survey (12 months)	500	1	15/60
	Eligibility Form	550	1	5/60
Father	Enrollment Survey	550	1	90/60

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